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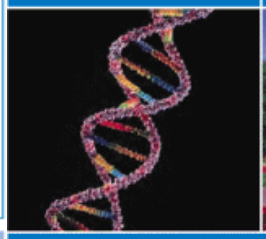

NEWSLETTER

July 2016, Volume XXVI, No. 4

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President's Message: Thanks to Our Members and Volunteers for Another Great Year!

My Fellow Members,

As the Chapter year comes to a close, I cannot help but look back on the tremendous accomplishments we have achieved as a Chapter this year. The list is a testament to the hard work of our enthusiastic volunteers who made them possible:

- 9 educational programs, including our first to originate from a geographic hub and be simulcast back to Boston.
- 23 programs held at our geographical outreach hubs in Providence, RI; Worcester, MA; and this year's newly established hub - Portsmouth, NH.
- 8 social events including our annual ski trip and two golf outings.
- 6 Young Professional events including our first YP event held in Providence.
- 4 membership drives at area companies.
- Over $8,500 raised for the National Kidney Foundation at the 2015 Kidney Walk.
- 2 new Student Chapters added, for a total of 13.
- $25,000 in scholarships awarded, bringing our five-year total to $93,570.
- And of course our flagship event, the ISPE Product Show broke all records for exhibitors, attendance and revenue which helps make all the other events possible financially.

But a great many of our Chapter's most significant accomplishments were behind the scenes and made through the tireless efforts of my fellow Board members:

- We provided input into an updated Charter with the Society that more accurately and fairly reflects the relationship between our two organizations. The new Charter is now being used by the Society as the baseline document for all the other Chapters and affiliates.
- We reviewed and enhanced our Chapter Bylaws to make them more appropriate for running the Chapter.
- We consolidated and updated our Chapter's Policies and Procedures to align with our current practices.
- We established a Finance Committee to oversee the Chapter's finances and budgeting process. That committee engaged a financial advisor to oversee the Chapter's investments and a new accounting firm to audit and manage our taxes.
- We established a new Communications Committee to oversee our website, newsletter, email notifications and social media. That committee has engaged a marketing consultant to help us develop and implement a strategic, long term marketing communications plan for the Chapter.
- We are moving forward with the creation of a 501(c)3 charitable foundation for our Scholarship Program. The new foundation will allow firms and individuals to make tax deductible contributions and enable us to expand the program.

Planning for the next Chapter year is well under way and we have some great educational and social events planned. Noteworthy will be our 25th Product Show on October 5th. We have lined up Travis McCready, President and CEO of the Massachusetts Life Sciences Center and the Honorable Richard E. Neal, House of Representatives, First District, Massachusetts as our keynote speakers at the plenary session to kick off what will be our biggest and best Show ever. And next Spring, we will have our 25th Anniversary Gala Dinner. This will be a Saturday night event to bring your significant other to, with dinner and dancing.

So I want to thank everyone who made this year special. As all can see, these are crazy times with lots of challenges facing our industry. There is a lot of uncertainty that comes with the election year, but our Chapter will continue moving upward and onward regardless of the outcome. Frankly, I try my best not to get caught up in all the banter but it gets tough with the incessant news coverage. There has been no shortage of controversy, negativity, and division within the US - with the whole world looking on.

I've always believed that America thrives because of its differences, and that good people can discuss their differences to find the common ground to keep things moving forward for the good of everyone. A great day to me is one where I get to meet a fellow Member over dinner and talk about why he or she was inspired to join ISPE; or a day when I can get a few different clients together and hear about their vision for changing the world and how we can change with them.

I can't guarantee much, but I can assure you that we as a Chapter will not change our basic principles, regardless of who leads the country. We will continue to be the leading Chapter in the Society and support our Members across the pharmaceutical and biopharmaceutical industry in the manufacture of quality medicines for patients.

Have a great summer!

H. Steven Kennedy
President, ISPE Boston Area Chapter

Chapter Bulletin Board

We Need to Hear from You by Friday, July 15 - Your Opinion Matters!

Help us serve you better by completing our communications survey by Friday's deadline. The survey takes only five minutes and ensures your input will be heard as we update the Chapter's marketing and communications strategy. We are striving to improve the way we communicate with our Members and publicize our events within the local biopharma and life sciences community. Our goal is three-fold: to do a better job of keeping Members informed about Chapter activities; to attract more Members and nonmembers to our events; and to increase Chapter membership. So take a few minutes and add your input to the mix - your feedback is important to us. Click this link to start: http://survey.constantcontact.com/survey/a07ecu5up5eipju6kp1/start. Thank you!

Vote in the ISPE Boston Area Chapter Board Election by July 31st!

Have you voted in the Chapter Board election yet? If not, please take a few minutes to vote on the electronic ballot here: http://survey.constantcontact.com/survey/a07ecu080h2ipijw50x/start. Please select the candidates who you feel would best serve on the ISPE Boston Area Chapter Board as Officers and Directors. Write in candidates are accepted. The election will conclude on Sunday, July 31, 2016 at 11:59 pm Eastern Time.

Product Show Booths Selling Fast - Don't Delay or You May Miss Out!

The ISPE Boston Area Chapter Product Show has been "Connecting the Hub of Life Sciences for a Quarter Century" - beginning way back in 1992! So join us on October 5, 2016 at Gillette Stadium in Foxborough, MA and help us celebrate our 25th Anniversary Product Show.

The ISPE Boston Area Chapter Product Show is the largest one-day show serving the life sciences industry in the world. Highlights include:

- Over 2500 life sciences professionals from the major manufacturing sites in the northeast
- Senior decision makers from operations, engineering, sourcing and compliance
- Attendees who are part of the decision process with open projects they are sourcing for
- Multiple opportunities to reconnect with current customers and prospect for new clients

Not to mention exciting educational programs, keynote address and special events throughout the day. Plus our famous After Party, this year at Splitsville in Patriots Place and featuring New England Patriots Defensive End Rob Ninkovich.

Booths and tables are going fast, with over 3/4 of the tables already sold. So don't delay any longer. To reserve your exhibitor space, simply go to the ISPE Boston Product Show page and Register today.

Join the Product Show Committee and Contribute to the Show's Success

The Product Show Committee (PSC) organizes and coordinates all activities associated with the Boston Area Chapter Product Show, the largest one-day gathering of biotech and pharma professionals in New England. In addition to an exciting educational program and keynote address, the Show offers attendees an unparalleled opportunity to network with industry peers and the Chapter's Board of Directors. With over 375 exhibiting companies and well over 2,500 attendees each year, the Product Show has earned its reputation as ISPE's best local show.

The Product Show Committee is responsible for all aspects of the Show, including soliciting exhibitors, assisting in the coordination of the educational program, attracting attendees and providing a host of activities throughout the day. Committee members work closely with other Chapter committees such as the Educational Program Committee, Communications Committee, Young Professionals Committee and Student Development Committee to ensure a successful event.

The PSC is made up of a motivated group of volunteers including several members of the Chapter Board of Directors. Committee members have varied backgrounds and expertise. All have the opportunity to work together in a fast- paced environment, have fun and participate in something very special every year.

The Product Show's continued success relies on the participation and creativity of PSC members. Innovative and cutting edge ideas keep the Show new and fresh every year and ensure a high degree of participation from the local community. New Committee members who want to get involved are always welcome. To join this award-winning team, please contact any member of the committee or the Chapter Board of Directors, or the Boston Area Chapter administrative offices at office@ispeboston.org.

Chapter Mentoring Program Up and Running

Could you benefit from the experiences of others or can you share your experiences to help a fellow Member? If so, the Chapter's new Mentoring Program is the place for you. Mentoring is a positive experience as well as a growth opportunity for both the mentor and mentee. Check out the new "Mentoring Program" tab on the Chapter website to learn more. All you have to do is register and the Chapter will pair you up.

Previous Issues

The mentoring program took almost a year to build and was a truly multidisciplinary effort by Membership Committee Chair Samir Gondalia, YP Committee Chair Chris Ciampa and Student Development Committee Co-Chair Brian Hagopian who worked together to develop and launch the program.

eNewsletter Ad Space Expanding - Sign Up Now!

Now that the Boston Area Chapter has grown to include over 1750 members located throughout all of New England, our eNewsletter ad space is also increasing. This gives Chapter Members a new opportunity to join the ranks of eNewsletter advertisers and gain valuable media exposure while helping to support the Chapter's expanding activities.

This additional ad space will disappear quickly so don't waste any time. Choose the option that works best for you - ads are available in two sizes and run for six months or a full year - then contact the Chapter office at (781) 647-4773 or office@ispeboston.org.

Support Your Chapter - Become a Sponsor!

Ever wonder how to become the Sponsor of a Chapter educational program or social activity? Or how to land one of the coveted eNewsletter or website advertising spots? To answer these questions, the Chapter has created a new website resource containing all the information you need to know to become a Chapter Sponsor.

We invite you to visit the sponsorship page at http://www.ispeboston.org/become_a_sponsor.html to explore the full range of sponsorship options available. Using the sponsorship application as your worksheet, you can view your savings as you select various combinations of sponsorship options - the more you choose, the bigger your discount!

So don't delay, visit http://www.ispeboston.org/become_a_sponsor.html and add your name to the growing list of Sponsors who gain valuable exposure while helping the Chapter better serve its Members. Or, if you'd rather, contact the Chapter office at (781) 647-4773 or office@ISPEBoston.org and we'll be happy to help!

Upcoming Chapter Events - Mark Your Calendar

Wednesday, July 20, 2016

ISPE Educational Programs 2017 Season Planning Meeting

Conference Center at Waltham Woods, Waltham, MA

EVENT SUMMARY

This summer, the Boston Area Chapter will receive valuable input on educational programs of interest to our Members through a survey which was launched in June. The Educational Program Committee would like YOUR help to finalize the educational program content for the upcoming Chapter year using the survey results. ISPE members are invited to join us on Wednesday, July 20, 2016 from 5:30 - 8:30 pm as the 2017 educational season is developed. Attendance and parking are free (we want your assistance) and dinner will be provided!

Click below for full information:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=592

Thursday, July 21, 2016

ISPE Young Professionals Red Sox Social

Blazing Paddles, Boston, MA

PROGRAM SUMMARY

Join the ISPE Boston Area Chapter Young Professionals in cheering on the Boston Red Sox as they take on the Minnesota Twins! We will be convening at Blazing Paddles @ Game On beforehand for ticket pickup, as well pre-game food and cash bar.

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=651

Wednesday, July 27, 2016

ISPE Student Chapter Committee Strategic Planning Session

Conference Center at Waltham Woods, Waltham, MA

EVENT SUMMARY

The Student Development Committee would like YOUR help in a strategic planning meeting and workshop for the Boston Area student chapters. ISPE members are invited to join us on Wednesday, July 27, 2016 from 5:30 - 8:00 pm as the 2017 student development season is created. Attendance and parking are free (we want your assistance) and dinner will be provided!

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=671

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Monday, August 8, 2016

ISPE Summer Golf Tournament

Lake Winnipesaukee Golf Club, New Durham, NH

EVENT SUMMARY

This year, for the 14th Annual Golf Tournament, the Social Committee is bringing us to a great location for a golf tournament - Lake Winnipesaukee Golf Club. Lake Winnipesaukee Golf Club is a private, 18-hole Clive Clark championship course that offers the golf experience of a lifetime - again and again. A stunning 700 mountain acres shelter almost 7,000 yards of magic. From magnificent bent grass tees and fairways to elegant greens, an exquisite experience nurtured by state-of-the-art technologies and the game's premier staff professionals.

Note: This event has SOLD OUT but you can contact the ISPE Boston office at office@ispeboston.org to be added to the waitlist.

Click below for full information:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=626

Thursday, September 8, 2016

ISPE Young Professional's Boston Harbor Boat Cruise

Massachusetts Bay Lines, Rowes Wharf, Boston, MA

EVENT SUMMARY

Join the ISPE Boston Area Chapter for our kick-off event of the season! New and returning members, young and old professionals are all welcome to enjoy in a night of socializing and networking with music as we tour the Boston Harbor waters.

This event is geared towards facilitating social and professional networking between people in the pharmaceutical, biotech, and life sciences fields. This is a great opportunity to meet other people from different areas of these exciting and diverse industries and get involved with the ISPE Boston Area Chapter.

Click below for full information and to register:

http://www.ispeboston.org/eventcal/calendar.html?action=display_event&oid=654

Sneak Preview of Upcoming Events - Save the Date!

Thursday, September 15, 2016
ISPE Accidental Project Manager
Alnylam Pharmaceuticals, Cambridge, MA

Thursday, September 22, 2016

ISPE RE-SHOWING: Accidental Project Manager
WPI, Worcester, MA; TBA, Portsmouth, NH

Wednesday, October 5, 2016
ISPE Boston's 25th Anniversary Product Show
Gillette Stadium Clubhouse, Foxborough, MA

The Sun Shows Up for Annual Spring Golf Outing

by Dan Kenny, Northeast Engineering

After what seemed to be weeks of rain, the weather finally broke and the sun shined for everyone at the Annual Spring Golf Outing. The event was held on May 11 at Ledgemont Country Club in Seekonk, MA. With the temperature in the mid to upper 60's and minimal cloud cover, it was a picture-perfect day for golf and networking with fellow Chapter Members and guests. The course was in great shape as always and the staff at Ledgemont did an amazing job of making us feel welcome for the second year in a row.

Ledgemont Country Club in Seekonk provided the venue for this year's Spring Golf Outing.

With a sold-out event again this year, the golfers were sent out with a full stomach thanks to an amazing spread for lunch at the clubhouse. Once on the course, Jim Grunwald (DPS Engineering) and Sherwood Butler (TRIA) started the festivities by crushing the golf ball straight down the fairway all day long and showing the rest of the field how it was done. Loud cheers from the amazing shots and groans from the near misses were heard all day long, sprinkled in with many, many laughs. As groups completed their rounds and headed for the clubhouse the laughs got louder and the stories got better over a beverage on the deck overlooking the beautiful course.

The course was in near perfect condition, as was the 19th hole where golfers gathered to celebrate their great (or not so great) round.

Once the last groups made it to the clubhouse, everyone made their way to the dining room where a fantastic buffet with a full carving station awaited the golfers and guests. After dinner was served, the awards took center stage. Awards were handed out for first, second and third place foursomes, longest drive (men/women), straightest drive (men/women) and closest to the pin (men/women). There was also a putting contest held along with a number of amazing raffle prizes. To end the event, there was a 50/50 raffle won by Nick Hanney, raising $575 for the Jimmy Fund (www.jimmyfund.org) which solely supports

Boston's Dana-Farber Cancer Institute, raising funds for adult and pediatric cancer care and research to improve the chances of survival for cancer patients around the world. Congratulations to all our winners!

Just a few of the 33 foursomes who enjoyed the day's festivities...

Winning Foursomes

- First: Bowdoin Construction (Chris Keeley, Dan DiLeonardo, Jeff Kern, Jason Helmer)
- Second: TRIA (Sherwood Butler, Dan Paquette, Herbie Aikens, Geoff Wilkinson)
- Third: Reflex Lighting (Paul Mustone, Joe Reilly, Joe Devlin)

Longest Drive

- Dennis Close
- Renee Driscoll

Straightest Drive

- Liz Von Goeler
- Joe Reilly

Closest to the Pin

- Tom Harvey and Dave Gallagher
- Janet Manchester

Putting Contest

- Bruce Durkee

The Social Committee would like to thank everyone who attended and helped make the tournament a big success, and the many sponsors who made the event possible: Albireo Energy, A/Z Corporation, Boston Analytical, Commissioning Agents, Crosspoint Engineering, DPS Engineering, ICQ Consultants Corporation, Northeast Engineering, Reflex Lighting Group, R.W. Sullivan Engineering, Siemens Building Technologies, Superior Controls, TRIA and Ultrafiltronics - A Wilkinson Company. Your support is greatly appreciated. The committee would also like to thank Erin and Katherine from the Chapter's admin team for helping with the organization of the tournament before and during. You are a vital part of our success!

Hope to see everyone at the "Sold Out" Summer Golf Outing to be held at Lake Winnipesaukee Country

Club on August 8. Also, be on the lookout for the Fall Social at Harpoon Brewery on October 27. See you soon!

Shire Hosts Single Use Educational Program and Pilot Plant Tour

by Joyce Chiu

The May educational program took place on the 19th at Shire Pharmaceuticals in Lexington and featured "Single Use: From Toddler to Adolescent" along with tours of Shire's Pilot Plant Operations (PPO) that highlighted single use technology.

After a networking reception with excellent food, 85 participants entered the large lecture hall where Chapter President H. Steven Kennedy welcomed the crowd and thanked event sponsor CAI and Shire for providing the venue and tour. Meeting Manager Chris Opolski then introduced the first speaker, Mark McElligott, Partner/Principal Process Engineer, Process Design Solutions and PDS Sandbox.

The May 19 "Single Use" program and tour at Shire attracted a cross-section of Chapter Members.

After describing some of the initial promises of Single Use Technology (SUT) in its toddler days, such as savings of 50 percent in capital investment and up to 30 percent in operational costs, Mark introduced the pitfalls that early adopters of SUT have since encountered. These include establishing SU component and characterization requirements, the criticality and relevance of such requirements for manufacturing and process development, the need for a technical quality agreement (TQA) with key vendors, as well as a cross-functional team focused on lifecycle management of SUT, including vendor change notifications.

Mark then expanded on each of these, the hidden costs associated with the implementation and integration of SUT, and provided detailed examples of areas that require subject matter expertise - materials science (in plastics), extractables and leachables, sterile tube welding, sealing and aseptic connection devices, gamma irradiation, and the larger business process of supply chain and vendor quality management.

He concluded his presentation by summarizing his recommendations - a site and process program for single use technology, a dedicated cross-functional team focused on SUT program management, and contingency plans for SU suppliers to stay on top of change management. With these in place, the benefits of SUT can be maximized. A brief Q&A followed during which Mark was able to provide additional detail.

(l to r) Meeting Managers Joyce Chiu and Chris Opolski with speakers Mark McElligot and Brad Ebel.

Chris then introduced the second speaker, Brad Ebel, PPO Upstream Manager, Shire Pharmaceuticals. Brad's presentation focused on the actual implementation of SUT with two technical case studies: Centrifuge redesign and Alternating Tangential Flow (ATF) redesign, both of which were required to create a semi-continuous (perfusion) biologics process based on SUT.

For the centrifuge, Brad outlined the initial challenge, why equipment had to be re-designed, how they worked closely with their vendor, and step by step, how the equipment was entirely revamped. He showed numerous photographs, which fit nicely into his narrative, and the audience got a very clear sense of the technical challenges, the trials and tribulations, and the eventual success. He also showed graphs depicting performance data leading to the eventual order of magnitude improvement in process performance. After years of effort, centrifuge is now one of the most reliable pieces of equipment at the PPO, which has been contamination free for over 4 years!

While centrifuge has been conquered, a new technology, ATF, has arisen. ATF offers distinct advantages, not the least of which is that it's much gentler on the cells, decreasing their stress while increasing viability and productivity. ATF is also a continuous process, efficient, scalable, and easy to use. Brad then went into more detail about how ATF works, its alternating pressure and exhaust cycles, and shared some process data. ATF has been introduced to the PPO with two vendor systems, Hyclone 50 L and Xcellerex 200 L bioreactors. Some of the challenges included warped plastic flange connectors, and stainless steel to C-flex molding, which were among the lessons learned.

Brad concluded his presentation by offering tips for evaluating new technologies. The most critical is to engage with a partner who is willing to make improvements on their equipment. He also provided the audience with guidance that SUT is not plug-and-play, it requires careful consideration for the human factor and an integrated approach, as Mark also emphasized, involving Supply Chain, Facilities, Engineering, Safety and Quality early in the process. The audience again asked many questions, which continued until after the formal ending of the evening.

Our two speakers, with two different yet complementary perspectives, one with an overall view, the other with practical case studies, provided the audience with intriguing insights into what it took to embrace and learn from failure and experience, while Single Use Technology has grown from a toddler to an adolescent. It was not only an educational but also a highly entertaining evening!

The Chapter would like to thank our excellent presenters and tour guides, event sponsor CAI, our generous host, Shire Pharmaceuticals, and Meeting Managers Joyce Chiu and Chris Opolski for making this very successful event possible.

ISPE Membership Drive Targets Sanofi Genzyme in Framingham

by Zeb Jones, Sanofi Genzyme

Sanofi Genzyme has over a hundred current members in the Boston Area Chapter that participate in Chapter events, serve on the committees, and volunteer in various capacities. To further strengthen the ISPE presence at Sanofi Genzyme, the Chapter's Membership Committee organized a membership drive at the company's Framingham Biologics Support Center on June 1. The purpose of this event was to familiarize Sanofi Genzyme employees with ISPE and illustrate the many benefits of membership. In addition, flyers for several summer Chapter events were distributed.

Katherine Batten from the Chapter's admin staff and Membership Committee volunteers and Sanofi Genzyme engineering manager Zeb Jones and engineer Mike Murphy set up the ISPE booth in the 68 New York Avenue cafeteria during the lunch hour when employees would have the time to stop and chat. They distributed ISPE membership brochures and flyers describing upcoming Chapter activities. Potential members were excited to hear about the professional development and career advancement opportunities and a number of them provided their contact information for follow up on joining ISPE.

ISPE Membership Committee volunteer Mike Murphy greets prospective member Jeffrey Lu at the Sanofi Genzyme Framingham Biologics ISPE membership drive.

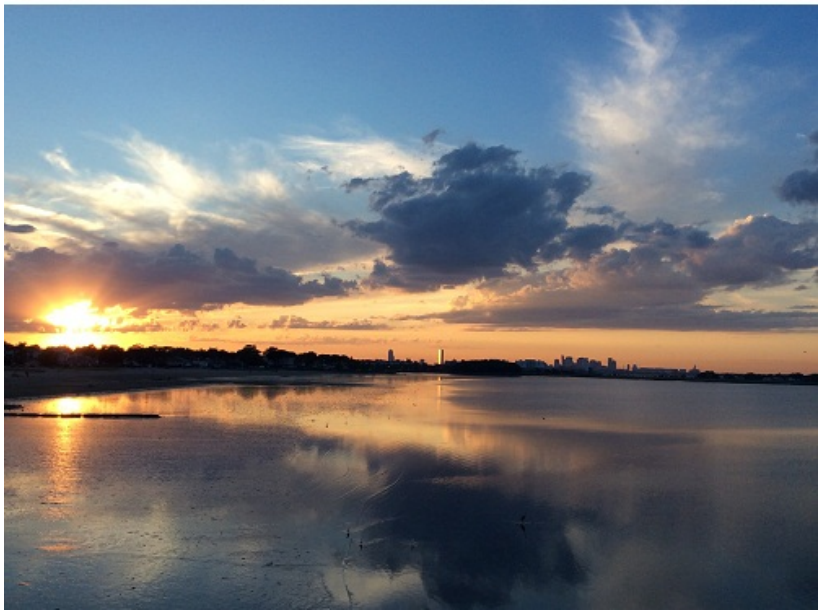
ISPE and the local Chapter provide a platform for New England pharmaceutical professionals to exchange practical knowledge with their peers, keep current on the latest trends in the industry, brush up on the basics, advance their technical knowledge, or simply meet and mingle with industry professionals who speak their language. We do this by hosting networking and educational events, career advancement workshops, professional publications, and by organizing the largest one-day life sciences Product Show in New England.

If anyone would like to help the Chapter attract new members by hosting a similar membership drive at their own company, please contact Membership Committee Chairs Ying Cai at ying.cai@biogen.com or Samir Gondalia at Samir.Gondalia@pfizer.com.

Hawaiian Luau on Quincy Bay Honors Chapter Volunteers

by Mina Jung, DPS

We had a great turnout for this year's Summer Social and Volunteer Appreciation Night, also known as the 2016 Hawaiian Luau on Quincy Bay. Squantum Yacht Club provided an easy breezy venue with amazingly friendly and accommodating staff. Our ISPE friends sipped drinks and mingled on the deck against a spectacular sun setting over the water and city views. The X-Isles provided mellow live steel drum and guitar music to accompany the festivities. The ice cream sundae bar, manned by Brett-the-Trooper-Scooper, provided our guests with welcome relief from...uhm...the Mai Tais, the perfect weather and the great food. Well, he was a welcome addition to the night, anyway!



Mother Nature provided perfect weather, ocean breezes and an awesome sunset to accompany this year's Summer Social.

Very much in the spirit of the evening, our expert pit masters served up a whole roasted pig (brought to the club in a travelling smoker) and served up fantastic BBQ fare, sauces and sides. We raised $450 for the very worthy charity, Community Servings, with special help from raffle winner Aarash Navabi who generously donated his winnings to the cause. And runner-up raffle winners Jack Campion and Matthew and Abigail Hildner took home tickets to a Red Sox game. It was a lovely event that drew both new and old friends. If you didn't make it to this one, we hope you'll join us next year.

Special thanks to our generous event sponsors: Albireo Energy, Boston Analytical, DPS, Hereva Consultants, JENSEN HUGHES, LJStar, New England Laboratories, Northeast Engineering, RW Sullivan, SPEC Process Engineering, and TRIA. And to Mother Nature for the perfect weather, the ocean breeze and the awesome sunset!

The dress code for the evening matched the Hawaiian luau theme and Chapter Members were happy to oblige!

Exciting YP Events Planned for Summer and Fall

by Christopher Ciampa, Thermo Fisher Scientific

Summer is fast approaching and that means we're ramping up to provide you with some fun social events to look forward to! This year, the YP's had a bit of a lull in May and June but you can expect the excitement

to heat up as we head into the summer months.

Make way for a trip to Fenway Park on Thursday, July 21 - this year's Red Sox outing is fast approaching! Come watch our fellow Sox take on the Minnesota Twins! Before the game, we'll meet at Blazing Paddles for food, drink and camaraderie. Tickets are only $25 for Chapter Members ($30 for non-members) and include the game and the pre-game meet-up. They're going fast, so don't delay, sign up today!

Our annual flagship event, the Boston Harbor cruise, is scheduled for Thursday, September 8, with details still being finalized. We're currently working with food vendors as well as a possible band in order to make this event the best yet, so keep an eye out for updates! Also in September, from an educational perspective, we are looking to partner with WPI on an evening event during their 5-day seminar on bioreactors. This would give our Student and YP Members a chance to see and learn about the bioreactors. Keep an eye out for details regarding this great opportunity.

Also in the planning phase is the "YP hour" at the October 5th Product Show. This year we're looking to offer some education in lieu of the social festivities we have sponsored in the past. We are considering a resume review session for students and young professionals entering the industry or in the process of changing jobs, as well as a panel discussion. Both will help students and young professionals gain the skills needed to land a job in our industry. Later the same month, we are hoping to host an event in partnership with the Tufts Gordon Institute. The likely topic will be a soft skill such as project leadership. Stay tuned for more information on both of these exciting events as October approaches.

Looking toward the end of 2016, we are planning dual track educational program for the November timeframe, potentially at Northeastern. The YP track will be "Regulatory 101: Jargon for Engineers - QC, QA, QS, RA: Really? Why?" Two speakers are currently planned, one from a pharma manufacturer and the other from a consulting firm. More information will follow in the coming months.

As always, we want to hear from you! If you have any suggestions or would like to attend one of the regularly scheduled YP committee meetings, please don't hesitate to reach out to me (christopher.ciampa@gmail.com). Happy summer and go Red Sox!

Need a Summer Internship, Co-Op or Full-Time Position? The Chapter Can Help!

by Brian Hagopian, Clear Water Consulting, and Paige Kane, Merck

The Chapter has been extremely busy helping students find employment, whether it's a summer internship, co-op or full-time position for students graduating and entering the work force. The Chapter offers local life science companies a free job posting service to help them fill vacancies. Check out the "jobs and internships" section of the Chapter website and "like" the Chapter's Facebook page to receive notifications when positions are posted. With the cooperation of several local firms looking to hire students, we have posted over 100 positions for our Student Members this spring! Remember, you have to be an ISPE member to access these positions.

The Chapter's Scholarship Program continues to help Student Members pay for the cost of their education. The most recent application period has closed and recipients will be selected and notified over the summer. The next application deadline is November 1. Applying is easy and your chances of receiving a scholarship are much higher than you might expect. You can apply here for the next round at any time prior to November 1 but don't wait until the last minute - a written referral needs to be submitted by the deadline.

While college campuses are taking a break over the summer, we will be working on our strategic plan for the coming year. We will be holding a brainstorming and planning session on July 27 to put plans in place for our Student Members for the upcoming year. All input is welcome, so please sign up and attend if you'd like to contribute your ideas.

If you need any further convincing of the benefits of being part of an active, professional network, check out our latest video and hear directly from some of our Young Professional Members at https://vimeo.com/148636910. And remember, Student Members can attend educational programs and YP social events for free! Hope to see you on campus or at an ISPE event soon!

Industry News In Review

by Jillian Willard, Genzyme, a Sanofi Company

Industry News In Review, a regular feature of the Boston Area Chapter Newsletter, presents a review of recent news items concerning companies in the pharma, biotech, medical device and related fields, with an emphasis on companies with a local presence and topics of special interest to Chapter Members.

Biogen and AbbVie Receive Positive Opinion in Europe for MS Treatment

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommended that Zinbryta (daclizumab), jointly developed by Biogen and AbbVie, be granted a marketing authorization for treatment of relapsing forms of multiple sclerosis (RMS). Zinbryta is a once-monthly, self-administered, subcutaneous investigational treatment for RMS and is also currently under regulatory review in the United States, Switzerland, Canada and Australia.

The CHMP positive opinion is now referred to the European Commission (EC), which grants marketing authorizations for centrally authorized medicines in the European Union. A decision from the EC is expected within the coming months. According to the CHMP opinion, the benefits of Zinbryta are its ability to reduce the annualized relapse rate (ARR), as well as the risk of 24-week confirmed disability progression. (Source: Biogen Website, 29 April, 2016)

AbbVie Acquires Stemcentrx, Expands Oncology Portfolio

AbbVie has announced it will acquire Stemcentrx and its lead late-stage asset rovalpituzumab tesirine

(Rova-T) currently in registrational trials for small cell lung cancer (SCLC). Rova-T is a novel biomarker-specific therapy that is derived from cancer stem cells and targets delta-like protein 3 (DLL3) that is expressed in more than 80 percent of SCLC patient tumors and is not present in healthy tissue. Registrational trials for third-line small cell lung cancer are expected to complete enrollment by the end of 2016. Rova-T is under investigation as a third-line treatment in SCLC, where there is no currently approved therapy. Rova-T also has been submitted to the FDA for Breakthrough Therapy designation.

AbbVie will acquire Stemcentrx for approximately $5.8 billion in cash and stock. AbbVie will pay approximately $2.0 billion of the transaction value in cash and fund the remaining portion with stock. In addition, Stemcentrx investors are eligible to receive up to $4 billion in cash for additional, success-based milestone payments for the achievement of certain regulatory and clinical developments. The transaction is expected to close in second-quarter 2016.

Beyond Rova-T, Stemcentrx has four novel compounds in clinical trials across several solid tumor indications including triple-negative breast cancer, ovarian cancer and non-small cell lung cancer. Stemcentrx has additional pre-clinical compounds advancing toward clinical trials in 2016 and a proprietary technology platform that leverages stem cell biology to identify and screen potential targets against live tumor tissue to more predictably advance discovery and development of new assets.

AbbVie's clinical oncology pipeline has 5 programs in late-stage development across more than 19 types of tumors. AbbVie already markets Imbruvica, a BTK-inhibitor approved to treat chronic lymphocytic leukemia (CLL), mantle cell lymphoma and Waldenstrom's macroglobulinemia, and Venclexta, a BCL-2 inhibitor approved to treat CLL in patients with 17p deletion. (Source: AbbVie Website, 28 April, 2016)

Abbvie Increases Potential Milestone Payments to Galapagos in Expansion of Cystic Fibrosis Collaboration

Galapagos and AbbVie have announced that the companies have expanded their agreement in cystic fibrosis (CF) to reflect the successful expansion of their CF portfolio. The companies have agreed to increase the potential milestones to Galapagos for Phase 1 and 2 achievements, bringing the remaining total milestones in the CF alliance up to approximately $600 million, from $350 million. Other key collaboration terms remain in place.

Galapagos and AbbVie aim to develop a triple CFTR combination therapy to address 90 percent of patients with CF. In order to bring a more effective therapy to patients, the companies have developed multiple candidates and backups for each of the three components of a potential triple combination. Triple combinations of CF compounds in the portfolio have consistently shown restoration of healthy activity levels. It is expected that a triple combination therapy from this collaboration will be tested in patients having a specific genetic mutation in 2017.

The collaboration began in September of 2013. Under the terms of the agreement, AbbVie made an upfront payment of $45 million to Galapagos. Galapagos has already earned $20 million in milestone payments to date and is now eligible to receive up to approximately $600 million in total additional payments for developmental and regulatory milestones, sales milestones upon the achievement of minimum annual net sales thresholds and additional tiered royalty payments on net sales, ranging from mid-teens to 20 percent. Galapagos will retain commercial rights to China and South Korea, and has an option to co-promote in Belgium, Netherlands, and Luxembourg.

Under the terms of the agreement, Galapagos is responsible for clinical development through to completion of Phase 2, AbbVie will be responsible for Phase 3. Since the beginning of the collaboration, AbbVie and Galapagos have created an expanded portfolio of candidate CF drugs which, in combination, may offer patients new therapy options. (Source: Galapagos Website, 29 April, 2016)

Biogen Intends to Spin Off Its Hemophilia Business

Biogen has announced it intends to spin off its hemophilia business as an independent, publicly traded company. The new company, to be named at a later date, will focus on the discovery and development of therapies for the treatment of hemophilia, with existing marketed products to include Eloctate and Alprolix, indicated for the treatment of hemophilia A and B, respectively. The new company is expected to continue to develop and commercialize Eloctate and Alprolix under Biogen's existing collaboration agreement with Swedish Orphan Biovitrum. Eloctate and Alprolix generated combined revenues of $640 million during the twelve-month period ended 31 March, 2016.

The new company plans to bring longer acting therapies utilizing the Xten technology into clinical development in the first half of 2017 and to accelerate the development of bispecific antibodies and hemophilia-related gene therapy programs. The new company also plans to conduct additional studies to confirm early data that suggest Eloctate's potential to rapidly induce immune tolerance in hemophilia patients who develop inhibitors.

The new company is expected to be headquartered in the Boston area. The new company will retain commercial rights for Eloctate and Alprolix for North America and for rest of the world markets outside of, essentially, Europe, North Africa, Russia and certain countries in the Middle East. Biogen is expected to provide transition services to the new company for some period of time and is expected to remain the manufacturer of Eloctate and Alprolix for the next three to five years. The full management team and board of directors of the new company will be named at a later date.

The spin-off is planned to be completed by the end of 2016 or early 2017, subject to the satisfaction of certain conditions, including, among others, final approval of Biogen's board of directors, receipt of a favorable opinion with respect to the tax-free nature of the transaction, and the effectiveness of a Form 10 registration statement that will be filed with the SEC. The spin-off is expected to be accomplished through a distribution of shares of the new publicly traded company to Biogen stockholders, in a transaction intended to be tax-free for U.S. federal income tax purposes. (Source: Biogen Website, 03 May, 2016)

Alnylam to Build New Manufacturing Facility in Norton, Massachusetts

Alnylam Pharmaceuticals recently broke ground on a biopharmaceutical manufacturing facility in Norton, Massachusetts. The facility will supply RNAi therapeutics for Alnylam's clinical and commercial needs. Construction on the 200,000 square foot manufacturing facility is expected to complete in 2018 and it will

initially employ approximately 150 new full-time employees. Alnylam has two new products currently in Phase 3 trials as well as multiple other products earlier in their pipeline. Alnylam's pipeline covers three areas: Genetic Medicines for the treatment of rare diseases, Cardio-Metabolic Disease, and Hepatic Infectious Disease. (Source: Alnylam Website, 28 April, 2016)

Intellia Therapeutics Announces IPO

Intellia Therapeutics, a company focused on the development of potential gene editing therapeutics using CRISPR/Cas9 technology, announced its initial public offering of 6,000,000 shares of common stock at a public offering price of $18 per share in May. Intellia's common stock began trading on the NASDAQ Global Market under the ticker symbol "NTLA" on 06 May, 2016 and is currently trading at over $26 a share. (Source: Intellia Website, 05 May, 2016)

Pfizer to Acquire Anacor Pharmaceuticals

Pfizer and Anacor Pharmaceuticals have announced that they have entered into a definitive merger agreement under which Pfizer will acquire Anacor for $99.25 per Anacor share, in cash, for a total transaction value, net of cash, of approximately $5.2 billion, which assumes the conversion of Anacor's outstanding convertible notes. The Boards of Directors of both companies have unanimously approved the transaction. Pfizer anticipates financing the transaction through existing cash and does not expect the transaction to impact its current 2016 financial guidance. Pfizer expects the transaction to be slightly dilutive to Adjusted Diluted Earnings Per Share (EPS) in 2017 with accretion to Adjusted Diluted EPS beginning in 2018 and increasing thereafter.

Under the terms of the merger agreement, a subsidiary of Pfizer will commence a cash tender offer to purchase all of the outstanding shares of Anacor. The closing of the tender offer is subject to customary closing conditions and the acquisition is expected to be completed in the third-quarter 2016.

Anacor's flagship asset, crisaborole, a differentiated non-steroidal topical PDE4 inhibitor with anti-inflammatory properties, is currently under review by the FDA for the treatment of mild-to-moderate atopic dermatitis, commonly referred to as eczema. The FDA accepted Anacor's New Drug Application for review in March. The Prescription Drug User Fee Act (PDUFA) goal date for the completion of the FDA's review is 07 January, 2017. If approved, Pfizer believes peak year sales for crisaborole have the potential to reach or exceed $2.0 billion. (Source: Pfizer Website, 16 May, 2016)

Biogen Receives Positive Opinion for Expanded Tysabri Use in MS Therapy in the EU

The Committee of Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended approval of a variation to the marketing authorization of Tysabri for use as a disease modifying therapy (DMT) for relapsing-remitting multiple sclerosis (RRMS) patients with highly active disease activity despite a full and adequate course of treatment with at least one DMT.

The CHMP opinion is based on real-world data from a Biogen study, which showed that Tysabri reduced multiple sclerosis disease activity and demonstrated a favorable benefit-risk profile, regardless of which prior DMT was used. This positive opinion follows April 2016 EC approvals that granted Tysabri unlimited validity for the marketing authorization in Europe and updated the European Union product information and physician/patient education materials. The new patient management plan provides an updated risk algorithm and guidelines to manage patient safety with regard to development of progressive multifocal leukoencephalopathy (PML) (Source: Biogen Website, 31 May, 2016)

Biogen's Remicade Biosimilar Approved in the European Union

The European Commission (EC) granted marketing authorization in the European Union (EU) for Flixabi, an infliximab biosimilar referencing Remicade. Flixabi was developed by Samsung Bioepis, the joint venture between Samsung BioLogics and Biogen. Flixabi is indicated for the treatment of adults with rheumatoid arthritis (RA), Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis, and psoriasis. Additionally, Flixabi can be used in patients 6 to 17 years old with severe, active Crohn's disease or severely active ulcerative colitis.

Flixabi will be the second anti-TNF biosimilar to be manufactured and commercialized by Biogen in the EU. Earlier this year, Samsung Bioepis received approval for Benepali (etanercept), a biosimilar referencing Enbrel. Biogen has since launched Benepali in several countries across the EU. Anti-TNF therapies are among the EU's largest drug expenditures.

As part of the submission, Samsung Bioepis provided a preclinical and clinical data package from head-to-head Phase 1 and Phase 3 clinical trials comparing Flixabi with the reference product Remicade. Following biosimilar approval guidelines from the European Medicines Agency, the Phase 3 clinical trial for Flixabi was performed to confirm equivalent efficacy, and to compare safety and immunogenicity with Remicade in a 54-week trial. (Source: Biogen Website, 31 May, 2016)

Amgen's Humira Biosimilar Wins Review by FDA Advisory Committee

Amgen announced that the FDA's Arthritis Advisory will review data supporting the company's Biologics License Application (BLA) for ABP 501, a biosimilar candidate Humira (adalimumab). The Committee will review analytical, clinical and pharmacokinetic data from studies involving ABP 501, including results from two Phase 3 comparative efficacy and safety studies conducted in both moderate-to-severe plaque psoriasis and moderate-to-severe rheumatoid arthritis. The Phase 3 studies met their primary endpoints showing clinical equivalence to adalimumab. Safety and immunogenicity of ABP 501 were also comparable to adalimumab. Data to support the transition of adalimumab patients to ABP 501 are included in the submission. The FDA has set a Biosimilar User Fee Act (BsUFA) target action date of September 25, 2016 for ABP 501. (Source: Amgen.com 13 June, 2016)

AstraZeneca Licenses Lesinurad to Ironwood Pharmaceuticals

AstraZeneca has announced it has entered into a licensing agreement with Ironwood Pharmaceuticals for the exclusive US rights to Zurampic (lesinurad). Zurampic was approved by the FDA in December 2015, in combination with a xanthine oxidase inhibitor (XOI), for the treatment of hyperuricemia associated with uncontrolled gout.

Under the terms of the agreement, Ironwood will acquire exclusive US rights to Zurampic. In addition,

Ironwood will gain the exclusive US rights to the fixed-dose combination of lesinurad and allopurinol. AstraZeneca plans to submit the fixed-dose combination program for regulatory review in the second half of 2016.

Ironwood will pay AstraZeneca sales-related and other milestone payments of up to $265 million and tiered single-digit royalties on Product Sales. AstraZeneca will manufacture and supply Zurampic, provide certain support and services to Ironwood and undertake the FDA post-approval commitment on their behalf. (Source: Astrazeneca Website, 26 April and 03 June, 2016)

BIND Therapeutics Files for Chapter 11 Bankruptcy Protection

BIND Therapeutics, a biotechnology company developing targeted and programmable therapeutics called Accurins, announced on 02 May, 2016 that the company filed a voluntary petition under Chapter 11 of the Bankruptcy Code in the U.S. Bankruptcy Court for the District of Delaware. The filing was made in an effort to minimize the impact from an accelerated repayment request from BIND's lender, Hercules Technology. BIND later announced an agreement was reached to pay-down $4 million in principal on the existing principal loan balance of approximately $12.4 million.

The bankruptcy filing and accelerated payment came after BIND announced a restructuring in April and a net loss for the first quarter of 2016 of $12.7 million, compared to a net loss of $8.3 million for the first quarter of 2015. BIND attributed the increase in net loss to an increase in clinical trial activities and the decrease in collaboration revenue during the first quarter of 2016.
The company intends to continue to manage and operate its business under the jurisdiction of the Bankruptcy Court and in accordance with the applicable provisions of the Bankruptcy Code and the orders of the Bankruptcy Court. (Source: BIND Therapeutics Website, 02, 09, 16 May, 2016)

New Biogen MS Drug Fails to Meet Endpoint

Biogen reported top-line results from a Phase 2 study evaluating its drug opicinumab (anti-LINGO-1), an investigational, fully human monoclonal antibody being developed as a potential neuroreparative therapy in people with relapsing forms of multiple sclerosis (RMS). In the study, opicinumab missed the primary endpoint, a multicomponent measure evaluating improvement of physical function, cognitive function, and disability. However, evidence of a clinical effect with a complex, unexpected dose-response was observed. Opicinumab also did not meet the secondary efficacy endpoint in SYNERGY, which evaluated the slowing of disability progression. (Source: Biogen Website, 07 June, 2016)

ARIAD Sells its European Operations and Out-Licenses European Rights to Iclusig

ARIAD Pharmaceuticals has announced it has completed the sale of its European operations to Incyte Corporation and entered into the previously announced license agreement for Incyte to exclusively license Iclusig (ponatinib) in Europe and other select countries. ARIAD transferred all rights to its EU operations to Incyte, which has acquired all shares of ARIAD Pharmaceuticals the parent company of ARIAD's European subsidiaries responsible for the commercialization of Iclusig in the licensed territory, for a payment to ARIAD at the closing of approximately $140 million. In addition, Incyte was granted an exclusive license to develop and commercialize Iclusig in the European Union and 22 other countries, including Switzerland, Norway, Turkey,
Israel and Russia. (Source: ARIAD Website, 02 June, 2016)

EMD Serono Expands Biopharmaceutical R&D Facility in Billerica

EMD Serono, the North American biopharmaceutical business of Merck KGaA, Darmstadt, Germany, announced a $12 million investment for the expansion of its R&D facility in Billerica, Massachusetts. The new building will span more than 30,000 square feet and accommodate approximately 120 new and current employees whose focus will be on R&D, with a focus on oncology, immuno-oncology and immunology. (Source: EMD Serono Website, 02 May, 2016)

Regulatory & Legislative Highlights

by Deepen Joshi, Sunovion Pharmaceuticals

Regulatory & Legislative Highlights, a regular feature of the Boston Area Chapter Newsletter. It reviews recent actions by the FDA and other regulatory agencies and governmental bodies, both federal and regional, with the potential to impact the pharma, biotech and device industries, and related fields.

Genentech's Tecentriq: First PD-L1 Inhibitor Approved by FDA

The FDA has approved Tecentriq (atezolizumab) to treat the most common type of bladder cancer, called urothelial carcinoma. This is the first product in its class (PD-1/PD-L1 inhibitors) approved to treat this type of cancer.

Tecentriq provides these patients with a new therapy targeting the PD-L1 pathway," said Richard Pazdur, M.D., director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "Products that block PD-1/PD-L1 interactions are part of an evolving story about the relationship between the body's immune system and its interaction with cancer cells."

Tecentriq targets the PD-1/PD-L1 pathway (proteins found on the body's immune cells and some cancer cells). By blocking these interactions, Tecentriq may help the body's immune system fight cancer cells. Tecentriq is the first FDA-approved PD-L1 inhibitor and the latest in the broader class of PD-1/PD-L1 targeted biologics approved by the FDA in the last two years.

Tecentriq is approved for the treatment of patients with locally advanced or metastatic urothelial carcinoma whose disease has worsened during or following platinum-containing chemotherapy, or within 12 months of receiving platinum-containing chemotherapy, either before (neoadjuvant) or after (adjuvant) surgical treatment. Urothelial carcinoma is the most common type of bladder cancer and occurs in the urinary tract system, involving the bladder and related organs. The National Cancer Institute (NCI) estimates 76,960 new cases of bladder cancer and 16,390 deaths from the disease in 2016.

The FDA granted the Tecentriq application breakthrough therapy designation, priority review status and accelerated approval for this indication. Tecentriq is marketed by Genentech based in San Francisco,

California. The Ventana PD-L1 (SP142) assay complementary diagnostic for Tecentriq is marketed by Ventana Medical Systems, based in Tucson, Arizona. (Source: FDA Website, 18 May, 2016)

FDA Approves Biogen's Zinbryta to Treat Multiple Sclerosis

The FDA has approved Biogen's Zinbryta (daclizumab) for the treatment of adults with relapsing forms of multiple sclerosis (MS). Zinbryta is a long-acting injection that is self- administered by the patient monthly.

MS is a chronic, inflammatory, autoimmune disease of the central nervous system that disrupts communication between the brain and other parts of the body. Zinbryta should generally be used only in patients who have had an inadequate response to two or more MS drugs because Zinbryta has serious safety risks, including liver injury and immune conditions.

Because of the risks, Zinbryta has a boxed warning and is available only through a restricted distribution program under a Risk Evaluation and Mitigation Strategy. The boxed warning also highlights other important risks of Zinbryta treatment including immune conditions, such as inflammation of the colon (non-infectious colitis), skin reactions, and enlargement of lymph nodes (lymphadenopathy). (Source: FDA Website, 27 May, 2016)

FDA Approves Ocaliva for Rare, Chronic Liver Disease

The FDA has granted accelerated approval for Ocaliva (obeticholic acid) for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA, or as a single therapy in adults unable to tolerate UDCA.

PBC is a chronic, or long lasting, disease that causes the small bile ducts in the liver to become inflamed, damaged and ultimately destroyed. This causes bile to remain in the liver, which damages the liver cells over time, and results in cirrhosis, or scarring of the liver. As cirrhosis progresses, and the amount of scar tissue in the liver increases, the liver loses its ability to function.

The FDA's approval is based on a reduction in the level of the biomarker alkaline phosphatase (ALP), as a surrogate endpoint which, based on multiple levels of evidence (mechanistic, clinical trial, epidemiologic), could be relied upon to be reasonably likely to predict clinical benefit, including an improvement in transplant free-survival.

Ocaliva was approved under the agency's accelerated approval program, which allows the approval of a drug to treat a serious or life-threatening disease based on clinical data showing the drug has an effect on a surrogate endpoint reasonably likely to predict clinical benefit to patients.

An improvement in survival, progression to cirrhosis, or other disease-related symptoms in patients being treated with Ocaliva has not yet been established, although a confirmatory trial is currently ongoing. Ocaliva is manufactured by Intercept Pharmaceuticals of New York, New York. (Source: FDA Website, 31 May, 2016)

FDA Approves First Generic Crestor

Watson Pharmaceuticals of Parsippany, New Jersey has received FDA approval to market generic rosuvastatin calcium, the first generic version of Crestor (rosuvastatin calcium) tablets. Generic drugs approved by the FDA have the same quality and strength as brand-name drugs. Generic drug manufacturing and packaging sites must pass the same quality standards as those of brand-name drugs.

Rosuvastatin calcium is in a class of drugs called statins, which work by stopping an enzyme called HMG-CoA reductase from making cholesterol. High LDL cholesterol, the so-called "bad cholesterol," is a known risk factor for heart attacks, strokes, and heart disease. High triglycerides may also increase the risk of heart disease. Statins should be used in addition to a diet restricted in saturated fat and cholesterol. (Source: FDA Website, 29 April, 2016)

FDA Approves First Drug to Treat Hallucinations and Delusions of Parkinson's Disease

The FDA has approved Nuplazid (pimavanserin) tablets, the first drug approved to treat hallucinations and delusions associated with psychosis experienced by some people with Parkinson's disease. As with other atypical antipsychotic drugs, Nuplazid has a Boxed Warning alerting health care professionals about an increased risk of death associated with the use of these drugs to treat older people with dementia-related psychosis. No drug in this class is approved to treat patients with dementia-related psychosis.

Nuplazid was granted breakthrough therapy designation for the treatment of hallucinations and delusions associated with Parkinson's disease. Nuplazid is marketed by Acadia Pharmaceuticals of San Diego, California. (Source: FDA Website, 29 April, 2016)

FDA Makes It Easier to Apply for Compassionate Use of Investigational Drugs

The FDA has finalized its efforts to streamline the process used by physicians to request expanded access, often called "compassionate use," to investigational drugs and biologics for their patients when there are no other options to treat their serious disease or condition. The goal of the changes was to reduce the procedural burdens on physicians and patients, including a new form, guidelines on how patients may be charged, and additional guidance on the program.

The Individual Patient Expanded Access Investigational New Drug Application will be used by physicians to request expanded access to investigational drugs for individual patients who suffer from serious or immediately life-threatening diseases and for whom no comparable or satisfactory alternative therapy is available. It is much shorter than the form previously used for individual patient expanded access requests and includes step by step instructions on how to complete it. (Source: FDA Website, 02 June, 2016)

New Members

Reema Alanber

Steve Yuan Bao

Dewey Beach, Lonza Biologics Inc

Sara Bell, EMD Millipore

Priyal Bhargava, University of Connecticut

Kevin Boudreau, Sanofi

Molly Brennan, Massachusetts Institute of Technology

Connor Brown, Assumption College

Robert Burns, Burns automation

Russell T. Carr, BS, MS, PhD, University of New Hampshire

Jeffrey Carter, PhD

Jesse Cobb, Lonza

Julie Ann Cooke, Thermofisher Scientific

Jeff Coop, BlueBird Bio

Keith Corbett, Cimetrics Inc

Benjamin Crewdson, M+W Group

Robert DeCoste, Biogen Idec

Brian Diluiso, Environments for Health

Kevin Doan, DPS

Lydia Dumont, Genzyme

Shaileen English, BS, Pfizer - Groton, CT

Tavis Frankel, ARC/Architectural Resources Cambridge

Dr. Nathalie Frau, Sanofi

Michael Gallogly, II, AMRI Inc

Yeimy Garcia, Sunovion Pharmaceuticals Inc

Jeremiah Genest, Genzyme

Justin Genest, The Chisholm Corp

Dave Giguere, B.A., Boston Research & Communications, Inc.

Dr. Ashutosh Gupta, Genzyme

Daniel Hage, BlueBird Bio

Ted Haley, III, Oliver M Dean Inc

Nancy C. Hamilton, SPX Lightnin

Erica Illescas, University of Connecticut

Kimberly Johnson, B.S., M.S., Temple University

Ross Jordan, Northeast Electrical Distributors

Timur Kurzej, Azzur Group LLC

Brian Lai, Azzur Group

Daniel Lanneville, Skanska USA Building Inc.

Amanda Levy, Northeastern University

Daniel Lowe, Critical Process Filtration Inc

Sybry Luma

Serena Luo, Northeastern University

Nathaniel MacDonald, CRB

David Christopher Mallonee, IPS-Integrated Project Services, LLC

John Maloney, Shire Pharmaceuticals

Steven Maniates, ChemE, RoviSys

Stefan Mash, Regeneron Pharmaceuticals Inc.

Cory Merchant, Regeneron Pharmaceuticals Inc.

Catherine Michalowicz, ARC/Architectural Resources Cambridge

Emily Mowatt, Worcester Polytechnic Institute

Jeremiah OConnor, Injectronics

Tej Pavoor, Moderna Therapeutics

Rhoda Pham, ImmunoGen Inc

Derek Pszybysz, VALSPEC

Christopher M. Puzzo, Barry-Wehmiller Design Group

John Reilly, Vertex Pharmaceuticals

Wiliam Rodny, BSCE, The Hope Group

Emma H. Sheils, Worcester Polytechnic Institute

Alan Shuhaibar, B.Eng., M.B.A., BellatRx Inc.

Hugh Sichel, University of Connecticut

Margaret Snow, Genzyme

Dirk E. Stevens, Fresenius Medical Care

Jennifer Strand, Shire HGT

Jessica Tatarczuk, Lonza

Ha To-Thai, DPS

Natasa Uzelac, ImmunoGen Inc

Edgardo T. Vega, Viaci Engineering & Consulting

William A. Washington, Rhodes Pharmaceuticals

Neil Webster, DPS Engineering

Leonard Weiser, Waters Corporation

Michael Raymond Wood, BSChem, Sanofi

Fred Woods, IV, Genzyme

Member Anniversaries

Over Twenty Years

- James V. Blackwell, PhD, MBA, The Windshire Group, LLC (22 years)
- Nicholas J. Casale, Biogen Idec (22 years)
- Patricia J. Charek, BW Kennedy & Co. (21 years)
- H Steven Kennedy, PE, Kennedy Strategic Consulting (21 years)
- James F. Miller, Jr., CRB (21 years)
- Jose M. Soto, Pfizer Inc (24 years)

Twenty Years

- John C. Masiello, Masy Systems Inc
- Daniel J. Mathien, Behringer Corporation

Fifteen Years

- Richard A. Anderson, Hill International, Inc.
- Michael A. Benedetto, Skanska
- Robert G. Cole, Hart Design Group
- David M. Simon, PE, CRB

Ten Years

- Bruce Coon, Norwich Pharmaceuticals, Inc. (Alvogen)
- Stella Lanphear, Commissioning Agents, Inc.
- John P. Piganelli, Fristam Pumps USA
- Charles J. Selig, IMA North America Inc

Five Years

- John Breese, EnDevor Scientific Recruiting
- Linda L. Burk, Pfizer R&D
- Ronald J. Calo, Mar Cor Purification
- Michael DePesa, Crosspoint Engineering
- Thomas Fernberg, Biogen Idec
- Andrew J. Liu, Organogenesis
- Andrew S. McLaren, DPS BioMetics Inc
- Fasha Onorato, R.W.Sullivan Engineering
- Paul George Provencal, Jr., Thermo Fisher Scientific

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